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Do older patients who refuse to participate in a self-management intervention in the Netherlands differ from older patients who agree to participate?

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ABSTRACT. Background and aims: Refusal of patients to participate in intervention programs is an important problem in clinical trials but, in general, researchers devote relatively little attention to it. In this article, a comparison is made between patients who, after having been invited, agreed to participate in a self-management intervention (participants) and those who refused (refusers). Compared with other studies of refusers, relatively more information could be gathered with regard to both their characteristics and reasons for refusing, because all potential participants were invited personally.

Methods: Older patients from a Dutch outpatient clinic were invited to participate in a self-management intervention, and their characteristics were assessed. Demographic data were collected, as well as data on physical functioning and lack of emotional support. People who refused to participate were asked to give their reasons for refusing. **Results:** Of the 361 patients invited, 267 (74%) refused participation. These refusers were more restricted in their mobility, lived further away from the location of the intervention, and had a partner more often than did the participants. No differences were found in level of education, age or gender. The main reasons given by respondents for refusing to participate were lack of time, travel distance, and transport problems. **Conclusions:** As in many studies, the refusal rate in this study is high, and seems to be related to physical mobility restrictions, travel distance and, partly, to availability of emotional support. These findings may be used to make the recruitment process more effective - for example, by offering transport to the location of the intervention.

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INTRODUCTION

Refusal of older patients to participate in intervention programs is an important problem in clinical trials (1-4). Many researchers have to deal with this problem, but relatively few devote explicit attention to it. Not having enough participants may, among other things, threaten the statistical power of a study, which is needed to detect the real effects of the intervention. If we know beforehand which patients are more likely to refuse participation, measures can be taken to encourage their participation. Why is it that so many patients who are potential participants refuse to participate in what are often well-developed interventions? Are patients who refuse to participate in an intervention different from those who agree?

As the number of older people with chronic conditions increases, the number of (randomized) clinical trials in which older participants are involved will probably also increase. An important part of these trials often concerns intervention studies, aimed at evaluating self-management programs, and the demands made on participants in self-management evaluation studies are, in general, relatively large. For example, patients have to travel to a hospital on several occasions, and meet other patients in group sessions. For many patients, this may be a burden, but we still know relatively little about which patients do refuse and how they differ from those who accept.

Most of the literature on older patients who refuse participation concerns health promotion intervention studies, where the definition of "non-participants" is used for older people who do not wish to participate (5-7). From the literature, it is also clear that people who do not want to participate are usually older (5, 6, 8-10), have a lower level of education (5, 7, 9), show fewer health be-

Key words: Aging, chronic condition, randomized trial, refusers, self-management.

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haviors such as the use of seat belts when driving or owning smoke alarms (11), are more likely to smoke (7), have a lower level of physical or mental health (5, 7, 9, 11, 12), are more likely to live further away from the location where the intervention takes place (6, 8, 10), are more likely to experience time constraints (5, 10), and perceive more social support in everyday and problem situations (13). The results with regard to gender are less consistent. Some studies found that refusers are more likely to be male (5), others that they were more likely to be female (7); yet others that there was no difference (6).

This article aims to add to this literature by comparing patients who refused to participate (refusers) and patients who agreed (participants), after they had been invited to participate in a self-management intervention. Because all patients were invited personally, we were able to gather a considerable amount of information with regard to their characteristics and reasons for refusing to participate.

As mentioned before, the demands of participating in the self-management intervention considered in this article were quite high. Participation required willingness to travel to a hospital on six occasions, once a week, to meet 10 to 15 other patients in group sessions lasting two and a half hours. Therefore, we first expected that people with greater physical problems, such as decreased mobility, or more chronic diseases, would be more likely to refuse to participate. In addition, we expected people who did not experience (many) health problems, and therefore had no need to attend a health program, would probably not participate because they expected no benefit from it.

Secondly, with regard to our self-management course, we asked participants to come to the location of the intervention themselves, no transportation being provided. We therefore expected that people who lived further away would be more likely to refuse to participate, because of the longer traveling time. Thirdly, during recruitment we asked people if they would like to participate in a "course". Therefore, because a course implies education and learning, we expected that people with a low level of education would be more likely to refuse to participate, because they might be deterred by this educational aspect. Fourthly, the self-management intervention for which the patients in this study were recruited was a group intervention, and being with a group of fellow-sufferers may be a source of social support, especially emotional support. We therefore expected that people who experienced a lack of emotional support would be more likely to participate, and that people who received enough emotional support would refuse more often. We had no expectations as regards age, because people aged 60 and over are rather heterogeneous with regard to physical and other resources: age itself is not the best predictor of functioning (14). We also had no specific expectations with regard to gender, since we did not expect to find differences

between men and women in their willingness to participate in a self-management intervention. However, we did compare the groups with regard to both age and gender.

METHODS

The procedures, research risks, and associated safeguards for this study were approved by the Independent Review Board of the University Medical Center Groningen.

Subjects

In the period from May 2003 to May 2004, potential participants were invited to take part in a self-management intervention, consisting of six weekly meetings in groups of 10-15 patients (15). Potential participants were selected on the basis of their medical records and personally invited. This took place at four wards of the Internal Medicine outpatient clinic of the University Medical Center Groningen, i.e., General Internal Medicine, Rheumatology, Endocrinology, and Lung Diseases. Eligibility criteria were, first of all, age 59 and over, and having a heart disease (angina pectoris or heart failure), a lung disease (COPD or asthma), arthritis, or diabetes. These diseases were selected because they are the most common chronic diseases among older people in the Netherlands (16). Other inclusion criteria were ability to communicate adequately in Dutch; experiencing problems with regard to ways of coping with their disease; and being physically able to attend a six-week course. Patients with a life expectancy of less than one year, already attending a disease-specific self-management program, participating in another study, or who were permanent residents of a nursing home were excluded. Patients with other diseases besides heart disease, lung disease, arthritis or diabetes were eligible for participation.

Procedure

During patients' first or control visit to one of the four wards of the hospital, their physicians were informed by means of a note in the medical records that these patients were considered to be eligible for the self-management intervention, and thus eligible to be invited to participate by the primary researcher (HE). Physicians' sole role was to ask their patients if they had time, after the appointment, to answer some questions asked by a researcher. If they gave their verbal consent, a short interview took place with the primary researcher, during which the Groningen Frailty Indicator (GFI) questions were asked, to collect as much information as possible about all patients, i.e., including refusers (14, 17). The Groningen Frailty Indicator (GFI) is a short, easy-to-administer 15-item instrument that assesses four domains of functioning: basic functions (3 items), physical functioning (7 items), lack of emotional support (3 items), and psychological functioning (2 items). Because not all eligibility criteria could be derived from medical records - for in-

stance, whether or not patients were experiencing problems in coping with their disease, or whether they were physically able to attend a six-week course - this information was obtained during the interview. At the end of it, if patients were considered to be eligible, they were invited to participate in a self-management intervention for chronically ill older people. They were given information about the structure of the intervention, i.e., that it concerned 6 weekly sessions of 2½ hours each, and about the content of the program - for instance, how to deal with fatigue or communicate with a physician. Patients who refused to participate were asked, by means of an open-ended question, to give their reasons. These reasons were categorized later on in the study.

Measures

In order to test our hypotheses, we used nine items of the GFI, i.e., those concerning physical functioning and lack of emotional support (Table 1). Each item is scored either zero (no problems) or one (problems), except for physical fitness, which has a score ranging from 0-10. Note that the four mobility items together form a subscale yielding an overall mobility score, and the three social items form a subscale yielding an overall lack of emotional support score (18). The data included the variables travel distance (in km), level of education (five categories, from 1=elementary,

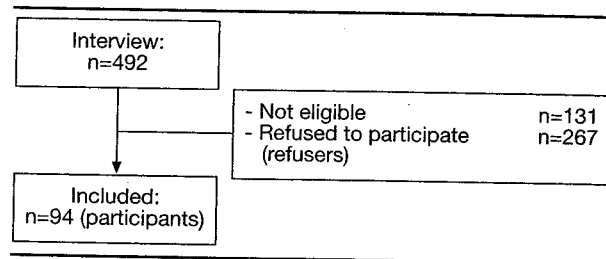


Fig. 1 - Enrolment procedure.

to 5=university) and having a partner (yes/no). The latter variable was also used as an indicator of emotional support. Data on age and gender were also collected.

Statistical analyses

First, refusers and participants were compared. T-tests were used for continuous variables, such as age. The variables partner and gender, and the 1-item variables of the GFI were analyzed by Pearson's Chi-square test or Fisher's Exact test. Mann-Whitney tests were used to compare the two groups with regard to travel distance and level of education. Secondly, logistic regression analysis was used to predict refusal to participate. All analyses were performed in SPSS 12.0.2 (19).

RESULTS

Subjects

Of the 492 patients who had the short interview with the primary investigator, 398 were excluded from participation. One hundred and thirty-one patients (26.6%) were not considered to be eligible for the self-management intervention, and were therefore not invited to participate (Fig. 1). The two main reasons for non-eligibility were that patients did not experience problems in coping with their disease ($n=83$), or that they were physically unable to attend a six-week course ($n=17$). Other reasons were: living in a nursing home ($n=3$); inability to communicate adequately in Dutch ($n=2$); admission to a hospital or rehabilitation center ($n=5$); or participating in another study ($n=2$). During the recruitment process, it also became clear that certain other patients were also not eligible: patients who were cognitively impaired ($n=8$); with severely impaired vision or hearing ($n=5$); with certain personality characteristics, such as being too talkative, which made them unsuitable for group sessions ($n=5$); and those who had recently been discharged from a psychiatric hospital ($n=1$).

Table 2 lists the characteristics of refusers and participants with regard to physical functioning, travel distance, level of education, partner status, lack of emotional support, age, and gender.

Two hundred and sixty-seven patients refused to participate (74.0%). As regards physical functioning, there was only a significant difference in mobility between refusers and par-

Table 1 - Items of Groningen Frailty Indicator (GFI) concerning physical and social functioning.

PHYSICAL FUNCTIONING

Mobility

Are you able to carry out these tasks single-handed without any help?

(Use of aids such as a walking stick, walking frame or wheelchair, is considered as independent)

1. shopping
2. walking around outside (around the house or to the neighbors)
3. dressing and undressing
4. going to the toilet

Physical fitness

5. What score do you give yourself for physical fitness? (scale 0 to 10)

Comorbidity

6. Do you take 4 or more different types of medicine?

SOCIAL FUNCTIONING

7. Do you sometimes experience an emptiness around you?
8. Do you sometimes miss people around you?
9. Do you sometimes have the feeling of being let down?

Scoring:

- | | |
|---------------|------------------------------|
| Question 1-4: | independent= 0; dependent= 1 |
| Question 6: | no= 0; yes= 1 |
| Question 7-9: | no= 0; sometimes and yes= 1 |

Table 2 - Characteristics of refusers and participants.

Characteristics	Refusers (n=267)				Participants (n=94)				p-value*
	% (n)	M	SD	Range	% (n)	M	SD	Range	
Physical functioning									
Mobility score		0.44	0.71	0-3		0.17	0.41	0-2	<0.001
Physical fitness score		6.1	1.53	1-10		6.1	1.30	0-8	0.977
Comorbidity	77.2 (206)				81.9 (77)				0.335
Travel distance (km)									0.031
≤10	33.3 (89)				45.7 (43)				
>10 - ≤20	23.6 (63)				18.1 (17)				
>20 - ≤30	9.7 (26)				11.7 (11)				
>30 - ≤40	13.9 (37)				13.8 (13)				
>40	19.5 (52)				10.6 (10)				
Education [†] (n)	(73)				(72)				0.106
Elementary	1.4 (1)				5.6 (4)				
Primary	19.2 (14)				30.6 (22)				
Secondary	68.5 (50)				51.4 (37)				
Tertiary	8.2 (6)				12.5 (9)				
University	2.7 (2)				-				
Partner	85.2 (225) [§]				64.9 (61)				<0.001
Lack of emotional support		0.96	1.09	0-3		1.17	1.18	0-3	0.109
Age		69.0	6.22	59-86		68.6	5.71	60-87	0.589
Gender									0.769
Male	39.0 (104)				37.2 (35)				

*p-value of t-tests, Chi-square tests, or Mann-Whitney test. [†]Classification based on Statistics Netherlands (CBS, 2005); [§]n=264; ^{||}sign $\alpha = 0.05$ (2-tailed).

Participants. Refusers had significantly more problems with regard to mobility than participants. No differences were found with regard to physical fitness or comorbidity. The finding with regard to physical fitness was unexpected, because refusers and participants did differ in their mobility problems.

A difference was found with regard to travel distance, i.e., refusers lived significantly further away. No statistically significant differences were found between refusers and participants with regard to education. It should be noted that the level of education of only a relatively small number of patients was known, i.e., 73 refusers and 72 participants. With regard to partner status, significantly more refusers than participants had a partner. No differences were found with regard to lack of emotional support, and there were no differences between refusers and participants with regard to age or gender.

To summarize, our expectations with regard to physical problems were partly confirmed, i.e., refusers had more problems with mobility than participants, but there were no differences in physical fitness or comorbidity. Our expectation with regard to travel distance was confirmed, i.e., refusers lived further away than participants. However, our expectation with regard to education was not confirmed, i.e., refusers did not have a lower level of education than participants, and our expectation with regard to emotional support was only partly confirmed, i.e., more refusers had a partner. However, no differences were found in lack of emotional support. We did not have any specific expectations with regard to age or gender, but no differences were found.

In order to know which of all the measured variables predicted refusal to participate, a logistic regression analysis was performed (Table 3). All variables were included, with (non-) participation as dependent variable. Because the level of education of only a relatively small number of patients was known, this variable was excluded from analysis. Analysis showed that mobility ($B=-1.01$, $p<0.001$) and having a partner ($B=-1.13$, $p<0.001$) were significantly related to participation. Travel distance was not a significant predictor.

Reasons for refusing to participate

Eighty percent of refusers gave a reason for their refusal (n=218). The main reasons were: no time to attend a six-

Table 3 - Logistic regression analysis.

Variable	OR (95% CI)	p-value*
Mobility	0.366 (0.208-0.643)	<0.001
Physical fitness	0.936 (0.779-1.125)	0.483
Comorbidity	1.70 (0.889-3.261)	0.108
Travel distance	0.883 (0.742-1.051)	0.161
Partner	0.324 (0.175-0.599)	<0.001
Lack of emotional support	1.05 (0.831-1.328)	0.677
Age	0.974 (0.932-1.018)	0.241
Gender	0.840 (0.488-1.443)	0.527

OR: odds ratio; CI: confidence interval. *sign= 0.05.

week course (19.3%), travel distance too far (19.3%), transport problems (12.4%), no need to attend a course (10.1%), and attending a course is too strenuous (7.8%). The people who mentioned not feeling the need to attend a course often added that they managed their disease well, or that they did not have problems in managing it. So, two main groups of refusers could be distinguished: those who had no time to attend a six-week course ($n=42$), and those who lived too far away ($n=42$). Because we were curious about the characteristics of these two groups, we performed some explorative analyses. First, we compared the two groups with regard to all variables. It appeared that the refusers who "lived too far away" did indeed live further away from the location of the intervention ($Z=-5.141$, $p=0.000$), but more of them had a partner ($\chi^2=4.100$, $p=0.043$) and more of them were women ($\chi^2=6.039$, $p=0.014$) compared with the refusers who "had no time". Each of the groups was also, separately, compared with participants. Refusers who "lived too far away" did live further away, and more of them had a partner, compared with participants (respectively $Z=-6.028$, $p=0.000$ and $\chi^2=13.583$, $p=0.000$); no differences were found between refusers who "had no time" and participants.

DISCUSSION

The aim of this study was to investigate the characteristics of patients who refused to participate in a self-management intervention, compared with patients who agreed. We collected demographic data, as well as data on physical functioning and emotional support from all patients who were invited to participate. We assumed that, on average, refusers would have more physical problems, live further away, have a lower level of education, and receive more emotional support. We had no specific expectations with regard to age or gender.

As is the case in many studies, the 74.0% rate of non-participation in this study was high, but it was even higher than in most intervention studies with an older study population, in which the rate varies from 7 to 50% (1, 5, 6, 9, 20, 21). However, it was comparable to the rate of the study carried out by Chang et al. (10), which concerned a 15-week relaxation response intervention (i.e., weekly group sessions in which various techniques were learned to elicit the relaxation response), in which 65% of screened patients refused to participate. In that study, the most important reasons for refusing to participate were "live too far away" and "time constraints". It is not quite clear why the rate of non-participation in our study was so high. One explanation is that the recruitment strategy used differed from that of most other studies, especially with regard to the way in which patients were invited to participate (usually by telephone or by letter in other studies), and the fact that patients were only invited to participate once (usually more than once in most studies). In addition, in our study, potential participants were first approached by their physi-

cians. In other studies, potential participants often first receive a letter signed by their physicians, and are then contacted by a researcher. Because experiences with other studies carried out in our hospital have shown that, the higher the demands on physicians with regard to recruiting, the lower the number of patients recruited, we chose to minimize the role of the physician in our recruitment process. As a consequence, we expected that the influence of the physicians' authority would be minimal. This is important, because we wanted to include patients who participated because of their own motivation rather than those who did so because they wanted to please their physician. However, a lower rate of non-participation may have been assumed because the recruitment strategy concerned a time- and effort-consuming face-to-face procedure.

In accordance with our expectations, differences were found between refusers and participants with regard to physical functioning. This finding is in accordance with the findings of Van Heuvelen et al. (13), who reported that in their study participants were functionally and physically more active. It may, however, be that especially these people with mobility problems would have benefited most from the program. No differences were found in physical fitness or comorbidity. With regard to physical fitness, this is remarkable, because a difference in mobility problems was found. Apparently, physical fitness was assessed on the basis of something other than mobility. An explanation for finding no difference with regard to comorbidity may be that we included patients aged 59 and over with one or more chronic diseases. In this population of chronically ill older patients, comorbidity is very common, as illustrated by our data which show that, on average, 79% of patients experienced comorbidity.

Also in accordance with our expectations, the two groups differed with regard to travel distance. Therefore, one way of making the recruitment process more successful would be to have more than one location for the intervention, so that patients could participate in a self-management intervention closer to their home. Contrary to our expectations, no differences were found between refusers and participants with regard to level of education. Our expectation regarding emotional support was partly confirmed: a significant difference was found with regard to having a partner, i.e., more of the refusers had a partner compared with participants. Partner status was related to emotional loneliness, i.e., people without a partner scored significantly higher on emotional loneliness than people with a partner (18), so it may be concluded that having a partner provides emotional support. However, with regard to the lack of emotional support, no differences were found between refusers and participants. Perhaps a partner provides a specific, or even unique, kind of emotional support. Logistic regression analysis showed that, of all the variables, mobility and having a partner had a unique association with (non-)participation.

The main reasons given by respondents for refusing to participate were: no time to attend a six-week course, travel distance too far, transport problems, no need to attend a course, and attending a course is too strenuous. This is similar to the study of Chang et al, where the main reasons for refusing were also "live too far away" and "time constraints" (10). When comparing the two main groups of refusers, i.e., "having no time" and "living too far away", the latter group did indeed live further away from the location of the intervention, more of them had a partner, and more of them were women. This supports interview observations, i.e., especially women mentioned that they depended on their husbands for transport, because they themselves did not have a driving license. These women may have refused to participate because they did not want to burden their husbands with driving to the location of the intervention for six consecutive weeks. This potential problem could be solved by providing some kind of meeting or activity for the husbands to do while their wives attended the course. No differences were found between participants and refusers who "had no time". Refusers who "lived too far away" did indeed live further away, but also more of them had a partner compared with the participants. Again, future studies could provide more than one course location, closer to participants' homes or could offer transportation.

Some limitations of our study should be mentioned. First, although we included quite a number and variety of variables in order to distinguish older refusers from participants, we did not gather information about motivational or psychological reasons for refusing to participate. However, these reasons may be related to the variables measured in our study. Future research should take this into consideration. Secondly, one question that arises from our results is why certain patients participated in the intervention even though they were expected to refuse because, for example, they had mobility or transport problems. This should be investigated in future research.

CONCLUSIONS

As in many studies, the rate of non-participation in this study was high. Refusal to participate seemed to be related to physical mobility restrictions, travel distance, and having sufficient emotional support. As a consequence, participants who were included in our self-management intervention were only a selection of the target population. In future self-management intervention studies, the above-mentioned characteristics of refusers should be taken into account - for example, by offering transport or providing some kind of activity for the partners of people who are unable to drive themselves to the location.

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